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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Choate, Hall & Stewart
Exchange Place
53 State Street
Boston, MA 02109

EXAMINER

GUZO, DAVID

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 12/16/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/928,463

Applicant(s)

LIU ET AL.

Examiner

David Guzo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 73-141 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 111-119 and 122-125 is/are allowed.
- 6) ☒ Claim(s) 73,74,79-92,94,95,107,108,120,121,126-130 and 134-141 is/are rejected.
- 7) ☒ Claim(s) 75-78, 93, 96-106, 109-110, 131-133 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Detailed Action

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 73-74, 79-87 and 90 are rejected under 35 U.S.C. 102(e) as being anticipated by Adams et al. (U.S. Patent 5,763,400).

Applicants claim an insect control agent (the insect pest can be a Lepidopteran insect such as *Manduca sexta*) comprising a baculovirus (which can be AcNPV) which directs the transcription of at least one RNA (can also be two separate complementary strands) that when present in an insect cell, forms a double stranded (ds) structure that inhibits expression of a target insect gene from a tissue (such as the alimentary canal) wherein the RNA inhibits expression of at least one essential insect gene (i.e. involved in development or neurotransmission), said insect control agents also comprising an agriculturally acceptable carrier.

Adams et al. (see whole document, particularly Columns 9-10, Example 2, Columns 14 and

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48-50, etc.) recites pest (insect) control agents (which can be formulated in an agriculturally acceptable carrier) comprising an expression vector (which can be a baculovirus such as AcNPV) containing sequences encoding antisense (and optionally sense) RNAs targeted against (and complementary to) a insect gene (which can be an essential gene such as that encoding ETH or a gene from the alimentary canal from *Manduca sexta*). Applicants and Adams et al. also recite methods of controlling insect pests comprising inhibiting the expression of an essential gene in said pest by introducing into cells of said pest a vector which expresses antisense sequences targeted against said essential gene. Therefore, Adams et al. teaches the claimed invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 126-129, 134, 138, 141 are rejected under 35 U.S.C. 102(a) as being anticipated by Fire et al.

Both applicants and Fire et al. (WO 99/32619, published 7/1/99, cited by applicants, see whole document, particularly pp. 10-12, paragraph bridging pp. 17-18, claims 1, 8, 14-17) disclose a method for controlling insect pests (which can be Lepidoptera) so as to reduce crop

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damage wherein said method comprises contacting a cell in the pest organism with a first RNA which hybridizes to itself or a target gene in the insect or with a second complementary RNA thereby forming a ds RNA within the cell wherein said ds RNA inhibits a gene (which can be a biological function involved in development, i.e. metamorphosis) expressed in the insect cell.

Fire et al. therefore teaches the claimed invention.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 91 is rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. in

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view of Miller et al.

Applicants claim an insecticidal composition comprising a baculovirus which directs transcription of at least one RNA that when present in an insect cell forms a ds structure that inhibits expression of at least one insect gene and an agriculturally acceptable carrier comprising an agent which can be a sticking agent or a UV protectant.

Adams et al. is cited in the above 102(e) rejection. While Adams et al. recites the use of agriculturally acceptable carriers for administration of the recombinant baculoviruses, Adams et al. does not recite use of specific constituents of said carriers such as UV protectants or sticking agents.

Miller et al. (U.S. Patent 6,235,278, issued 5/22/01, filed 10/1/97, see whole document, particularly column 21) recites the use of standard agriculturally acceptable carriers for administration of recombinant baculovirus insect control agents and the use of agents such as UV protectants and sticking agents in said agriculturally acceptable carriers.

The ordinary skilled artisan, seeking to apply the recombinant baculoviruses recited by Adams et al. would have been motivated to include standard additives such as UV protectants or sticking agents (as recited by Miller et al.) into the agriculturally acceptable carriers recited by Adams et al. for their known and expected benefits (e.g. increasing the potency or efficacy of the baculovirus pest control agent) as recited by Miller et al. It would have been obvious for the

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ordinary skilled artisan to do this because the use of agents such as UV protectants or sticking agents in agriculturally acceptable carriers increases the efficacy of the biocontrol agents such as recombinant baculoviruses contained in said carriers (as recited by Miller et al.). Given the teachings of the cited references and the level of skill of the ordinary skilled artisan at the time of applicants' invention, it must be considered that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Claims 130, 135 and 139-140 rejected under 35 U.S.C. 103(a) as being unpatentable over Fire et al. in view of Adams et al.

Applicants claim a method of controlling insects, said method comprising contacting (with a baculovirus such as *Autographa californica* MNPV (AcMNPV)) a cell in an insect with a first RNA whose sequence corresponds to at least a portion of one gene endogenous in the insect, wherein the first RNA hybridizes either with itself or with a second RNA with which the cell is also contacted, thereby forming a ds structure within the cell that inhibits expression of at least one gene expressed in the cell. The insect to be controlled can include a lepidopteran pest such as *Manduca sexta*, the composition can be applied to organisms (such as plants) that the pest feeds upon and the target gene can be one involved in neurotransmission or a gene from tissue in the alimentary canal.

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Fire et al. is applied as in the above 102(a) rejection. Fire et al. additionally teaches that a viral construct packaged into a viral particle can be used to deliver the RNA molecules which form the ds structure in the target cell (p. 14) and Fire et al. teaches that the RNAs can be formulated in an agriculturally acceptable composition to be applied to crops on which insect pests feed (paragraph bridging pages 17-18 and page 21). Fire et al. does not specifically teach that the viral vector be a baculovirus (such as AcMNPV) and does not teach the specific lepidopteran pest species to be targeted

Adams et al. (Cited in the above 102(e) rejection) recites the generation of baculovirus vectors (which can be AcMNPV) to deliver RNA molecules which can form ds structures in the target host insect cell (which can be from an insect pest such as *Manduca sexta*) and wherein said structures inhibit insect gene expression (i.e. the ETH gene or a gene from the alimentary canal).

The ordinary skilled artisan, seeking to choose a viral vector for control of insect pest species such as *Manduca sexta*, would have been motivated to choose a baculoviral vector for delivery of the target insect gene inhibitory RNAs recited by Fire et al. because Adams et al. teaches that baculoviral vectors (including AcMNPV) for control of insect pests such as *Manduca sexta* are desirable because the occluded baculoviral virions can be easily incorporated into insecticidal compositions and applied to crops (see Example 18). It would have been obvious for the ordinary skilled artisan to do this because Adams et al. teaches that baculoviral

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vectors such as AcMNPV are easily useable in insecticidal compositions and can be readily applied to crops to be protected. Given the teachings of the prior art and the level of skill of the ordinary skilled artisan at the time of applicants' invention, it must be considered that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 88-89, 94-95, 107-108, 120-121 and 136-137 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants recite a pest control agent comprising a baculovirus that directs transcription of an RNA that is species specific in that it does not show more than approximately 80% homology with any known vertebrate gene. Applicants also recite a method of controlling insects comprising administering contacting cells in said insect with said pest control agent. The claims read on a genus of RNA molecules and a method of using said RNA molecules.

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The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

In the instant case, applicants do not reduce to practice any sequence with the claimed properties. It must be considered that the members of the genus would vary widely as the claims encompass any RNA sequence (of potentially any size) which binds to any target insect gene sequence so as to inhibit expression of said sequence and wherein the claimed sequence does not show more than 80% homology with any known vertebrate gene. Given that the sequence of each different insect target gene will be different and given that the sequence of the claimed RNA will need to be ascertained based upon its homology to the target gene and its **lack of homology** to any known genes from any other species or any known vertebrate gene, it must be considered that the structure of one member of the genus would not be predictive of the structure of any other member. Applicants claim the members of the genus by sequence but provide no guidance on what structural elements (if any) the sequences of the genus would share. The sequence, to be active, must bind to the target gene sequence or to itself so as to generate a ds

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RNA capable of inhibiting the target gene. It is unclear if all ds RNAs will be able to exert this effect and it must be considered that the individual sequences having the desired effect (and having the recited absence of homology with other genes) will need to be empirically determined. Given the above analysis, it must be considered that the skilled artisan would not conclude that applicants were in possession of the claimed genus.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 92 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 6,326,193 (hereafter the '193 patent). This is a double patenting

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rejection.

Claim 92 of the instant application recites the same recombinant baculovirus as that recited in claim 1 of the '193 patent.

Claims 80, 83, 84 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 80, 83 and 84 are broader than the claim (Claim 73) from which they depend because while claim 73 recites an "insect control agent", claim 80, 83 and 84 recite that the target cell or gene is from a "target pest organism" which is broader in scope.

Claims 111-119 and 122-125 are allowed.

Claims 75-78, 93, 96-106, 109-110 and 130-133 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-1906. The

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examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Faxes may be sent directly to the examiner at (703) 746-5061.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David Guzo
December 9, 2002

DAVID GUZO
PRIMARY EXAMINER
David Guzo